Opportunity Title: Modeling and Simulation Fellowships - CDER
Opportunity Reference Code: FDA-CDER-2015-0105

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2015-0105

How to Apply

A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description

Specifically, DQMM provides expertise in advanced quantitative methods for the generic drug research program and conducts GDUFA regulatory science and research activities based on quantitative approaches. Some of the responsibilities residing in DQMM include providing quantitative method support for guidance development, abbreviated new drug application (ANDA) reviews, citizen petitions, controlled correspondence, pre-ANDA meetings, and methodology development for bioequivalence evaluation, active ingredient sameness demonstration and postmarketing safety surveillance. This Division coordinates modeling, simulation, data analysis and data mining and establishes the scientific computing infrastructure for OGD. DQMM is also developing innovative quantitative approaches to improve regulatory decision making for generic drugs by fully utilizing the large amount of data available to FDA.

The Division of Quantitative Methods and Modeling (DQMM) in the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD) in the Food and Drug Administration is a fast-paced, dynamic scientific environment with opportunities to work with dedicated, energetic senior researchers who want to make a difference and improve public health. We are looking for Oak Ridge Institute for Science (ORISE) fellows to participate in research activities that support our mission of providing high quality generic drugs to the American consumer.

The ORISE position(s) in DQMM provides an outstanding opportunity to learn and apply quantitative analysis, modeling, and simulation to support the aforementioned activities. Research activities include, but not limited to, the following areas:

• Modeling and simulation of modified release solid oral products (including absorption models, in vitro - in vivo correlations and pharmacokinetic/pharmacodynamic [PK/PD] modeling) to ensure the consistency and quality of bioequivalence recommendations from OGD.

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• Model-based delivery system assessment.
• Innovative approaches to establish active ingredient sameness/pharmaceutical equivalence for complex drug substances.
• In vitro bioequivalence analyses.
• Application of physiologically based pharmacokinetic (PBPK) models for non-oral drug products to help develop new bioequivalence methods for locally acting drug products administered via non-oral routes of administration.
• PK/PD modeling of narrow therapeutic index drugs and complex drug products and clinical trial simulation to aid risk-based bioequivalence evaluation.
• Conventional and model-based meta-analysis on drugs within same class or different classes.
• developing/applying novel analysis approaches to detect and assess safety signals of generic products.
• Developing systems pharmacology-based methodologies to understand and predict drug actions underlying both therapeutic effect and adverse reactions.
• Researching and building data infrastructure and analysis tools to increase ANDA review efficiency and quality by integrating information from FDA datasets.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. There are multiple full-time postitions available. The initial appointment is for one year, but may be renewed upon the recommendation of FDA and contingent on the availability of funding. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications Ph.D., M.D., Pharm.D., or other qualified scientists holding advanced degree(s) in pharmacometrics, Clinical Pharmacology, Pharmaceutical Sciences, Chemistry, Statistics, Life Science, or Engineering.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (1 👁)